# ATTACHMENT 64

# **Traditional 510(k) Notification**



## **Re-manufactured EndoWrists**

Rebotix, LLC Saint Petersburg, FL

> Exhibit DX 255

HIGHLY CONFIDENTIAL REBOTIX170421

## Module (A) Administration

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#### Notes on organization:

This submission has been organized into eleven (11) self-contained modules that mirror the organization of FDA's RTA checklist. Page numbers and attachments within a given module are prefixed with the letter of that module (e.g. "Attachment E-2"). The ultimate goal is to apply a logical and intuitive organization structure that will facilitate an efficient review. Bookmarks have also been implemented in order to aid navigation within each module.



445 Apollo Beach Blvd, Apollo Beach, FL 33572

Phone: (813) 645-2855 FAX: (813) 645-2856

Date: December 18, 2014

Document Mail Center (W066-06) Center For Devices and Radiological Health Food and Drug Administration 10903 New Hampshire Ave Silver Spring, MD 20993

Re: Traditional 510(k) Submission

Dear Madam or Sir:

In accordance with Title 21 CFR 807.81, we are notifying you of our client's intent to manufacture, package, and put into commercial distribution:

Trade Name: Re-manufactured EndoWrist

Common Name: Endoscopic instrument control system, endoscopic instruments and

accessories Class: II

Panel: General & Plastic Surgery

Enclosed is one paper copy of the original submission. Per the instructions accessed at <a href="http://www.fda.gov/cdrh/elecsub.html">http://www.fda.gov/cdrh/elecsub.html</a>, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission. There have been no prior submissions for the Re-manufactured EndoWrist which FDA determined were NSE, were deleted or withdrawn.

If you need any additional information, please contact the writer.

Sincerely,

Ryan Burke

Pyin Bure

## **List of Attachments**

Medical Device User Fee Cover Sheet	Attachment A-1
CDRH Premarket Review Cover Sheet (Form 3514)	Attachment A-2
Additional Model Numbers (Form 3514)	Attachment A-3
Indications for Use	Attachment A-4
510(k) Summary	Attachment A-5
Truthful and Accuracy Statement	Attachment A-6
Standards Data Report (Form 3654)	Attachment A-7

<u>Attachment A-1 – Medical Device User Fee Coversheet</u>

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Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER:  MD6079161  Write the Payment Identification number on your check.
A completed cover sheet must accompany each original appl payment is sent by U.S. mail or courier, please include a cop Payment and mailing instructions can be found at: http://www	y of this completed form with payment.
COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  REBOTIX LLC 539 Pasadena Ave S	Joe Morrisson 2.1 E-MAIL ADDRESS usagent@ajwtech.com
Saint Petersburg FL 337072125 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1329	2.2 TELEPHONE NUMBER (include Area code) 727-3434914 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
3. TYPE OF PREMARKET APPLICATION (Select one of the please refer to the application descriptions at the following we http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidSelect an application type:  [X] Premarket notification(510(k)); except for third party  [] 513(g) Request for Information  [] Biologics License Application (BLA)  [] Premarket Approval Application (PMA)  [] Modular PMA  [] Product Development Protocol (PDP)  [] Premarket Report (PMR)  [] 30-Day Notice	eb site: dance/GuidanceDocuments/ucm345263.htm 3.1 Select a center [X] CDRH [] CBER 3.2 Select one of the types below [X] Original Application Supplement Types: [] Efficacy (BLA) [] Panel Track (PMA, PMR, PDP) [] Real-Time (PMA, PMR, PDP)
<ul> <li>4. ARE YOU A SMALL BUSINESS? (See the instructions for status)</li> <li>[] YES, I meet the small business criteria and have submitte the required qualifying documents to FDA</li> <li>4.1 If Yes, please enter your Small Business Decision Num</li> </ul>	d [X] NO, I am not a small business
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO I ESTABLISHMENT REGISTRATION FEES THAT ARE DUE [X] YES (All of our establishments have registered and paid register and pay the fee within 30 days of FDA's approval/cle. [] NO (If "NO," FDA will not accept your submission until you submission will not be processed; see http://www.fda.gov/cdr	FDA. HAS YOUR COMPANY PAID ALL TO FDA? the fee, or this is our first device, and we will arance of this device.) I have paid all fees due to FDA. This
aualified small husiness including any affiliates	

Site: null Page 2 of 2

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[] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only [] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[] YES [X] NO

#### PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

\$5,018.00 15-Dec-2014

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

<u>Attachment A-2 – CDRH Premarket Review Cover Sheet</u>

Form Approval DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION OMB No. 0910-0120 Expiration Date: December 31, 2013 CDRH PREMARKET REVIEW SUBMISSION COVER SHEET See PRA Statement on page 5. User Fee Payment ID Number FDA Submission Document Number (if known) Date of Submission 12/18/2014 MD6079161 TYPE OF SUBMISSION **SECTION A PMA PMA & HDE Supplement** PDP 510(k) Request for Feedback Original PDP Original Submission: Original Submission Regular (180 day) Pre-Submission Premarket Report Special Notice of Completion Informational Meeting Panel Track (PMA Only) Modular Submission Amendment to PDP Special Submision Issue Meeting Abbreviated (Complete section I, Page 5) Amendment 30-day Supplement Day 100 Meeting Report 30-day Notice Agreement Meeting Additional Information Report Amendment 135-day Supplement Determination Meeting Third Party Real-time Review Licensing Agreement Study Risk Determination Amendment to PMA & HDE Supplement Other (specify): Other IDE **Humanitarian Device Class II Exemption Petition Evaluation of Automatic Other Submission Exemption (HDE)** Class III Designation (De Novo) Original Submission Original Submission Original Submission 513(g) Original Submission Amendment Amendment Additional Information Other Additional Information (describe submission): Supplement Supplement Report Report Amendment Have you used or cited Standards in your submission? Yes ☐ No (If Yes, please complete Section I, Page 5) SUBMITTER, APPLICANT OR SPONSOR **SECTION B** Company / Institution Name Establishment Registration Number (if known) Rebotix, LLC Division Name (if applicable) Phone Number (including area code) 727-343-4914 Street Address FAX Number (including area code) 539 Pasadena Avenue South City State / Province ZIP/Postal Code Country St. Petersburg FL 33707 USA Contact Name Joe Morrison Contact Title Contact E-mail Address joemorrison@rebotix.net Operations Manager **SECTION C** APPLICATION CORRESPONDENT (e.g., consultant, if different from above) Company / Institution Name AJW Technology Consultants, Inc Division Name (if applicable) Phone Number (including area code) (813) 645-2855 Street Address

Contact Title Contact E-mail Address Regulatory and Quality Consultant rburke@ajwtech.com

FAX Number (including area code)

(813) 645-2856

State / Province

FL

PSC Publishing Services (301) 443-6740 Module A - Page 9 of 43

Country

Page 1 of 6 Pages

USA

ZIP Code

33572

FORM FDA 3514 (1/13)

445 Apollo Beach Blvd

City

Apollo Beach

Contact Name Ryan Burke

REASON FOR APPLICATION - PMA, PDP, OR HDE **SECTION D1** New Device Change in design, component, or Location change: specification: Manufacturer Withdrawal Software / Hardware Sterilizer Additional or Expanded Indications Request for Extension Color Additive Packager Post-approval Study Protocol Material Request for Applicant Hold Specifications Request for Removal of Applicant Hold Other (specify below) Report Submission: Request to Remove or Add Manufacturing Site Annual or Periodic Post-approval Study Labeling change: Process change: Adverse Reaction Indications Manufacturing Packaging Device Defect Sterilization Instructions Amendment Performance Characteristics Other (specify below) Shelf Life Change in Ownership Trade Name Change in Correspondent Other (specify below) Response to FDA correspondence: Change of Applicant Address Other Reason (specify): **SECTION D2 REASON FOR APPLICATION - IDE** Change in: New Device Response to FDA Letter Concerning: New Indication Correspondent / Applicant Conditional Approval Addition of Institution Design/Device Deemed Approved Expansion / Extension of Study Deficient Final Report Informed Consent IRB Certification Manufacturer Deficient Progress Report Termination of Study Manufacturing Process Deficient Investigator Report Withdrawal of Application Protocol - Feasibility Disapproval Protocol - Other Request Extension of Unanticipated Adverse Effect Time to Respond to FDA Notification of Emergency Use Sponsor Compassionate Use Request Request Meeting Report submission: Treatment IDE Request Hearing Current Investigator Continued Access Annual Progress Report Site Waiver Report Final Other Reason (specify): **SECTION D3 REASON FOR SUBMISSION - 510(k)** New Device Additional or Expanded Indications Change in Technology Other Reason (specify):

FORM FDA 3514 (1/13) Page 2 of 6 Pages

**SECTION E** ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS Summary of, or statement concerning, Product codes of devices to which substantial equivalence is claimed safety and effectiveness information NAY 510 (k) summary attached 8 510 (k) statement Information on devices to which substantial equivalence is claimed (if known) 510(k) Number Trade or Proprietary or Model Name Manufacturer K063220 DA VINCI S SURGICAL SYSTEM-V1.1, INTUITIVE SURGICAL, INC. MODEL IS2000 INTUITIVE SURGICAL DA VINCI SI INTUITIVE SURGICAL, INC. K081137 2 SURGICAL SYSTEM: MODEL IS3000 3 3 3 5 5 5 6 6 6 PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS **SECTION F** Common or usual name or classification name System, Surgical, Computer Controlled Instrument Trade or Proprietary or Model Name for This Device Model Number Potts Scissors 420001 Large Needle Driver 2 420006 420007 Round Tip Scissors 3 DeBakey Forceps 420036 4 Long Tip Forceps 5 420048 FDA document numbers of all prior related submissions (regardless of outcome) 5 6 8 9 10 12 11 Data Included in Submission Laboratory Testing Animal Trials Human Trials **PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS SECTION G** C.F.R. Section (if applicable) Device Class Product Code NAY 876.1500 Class I Class II Classification Panel Class III Unclassified General & Plastic Surgery EndoWrist® Instruments, including scissors, scalpels, forceps, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing. The Instrument is for use only with the Intuitive da Vinci® S and da Vinci® Si Systems (Endoscopic Instrument Control System).

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Case 3:21-cv-03496-AMO	<u>Document 2</u>	2 <u>30-14 Filed 05/17</u>	<u> 7/24                                    </u>	<u> Page 14 o</u>	<u>† 45                                    </u>
Note: Submission of the information entered in Section H doe	es not affect the	FDA Document Number (If Kno	own)		
need to submit device establishment registration.					
SECTION H MANUFACTURING / F	PACKAGING / ST	ERILIZATION SITES REL	_ATINC	TO A SUBM	ISSION
Facility Establishment Identifier (F	EI) Number	Manufacturer	Псо	ntract Sterilizer	
Add Delete		Contract Manufacturer	=	packager / Relab	eler
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Reboula, LLC					
Division Name (if applicable)		Phone Number (including area	a code)		
		727-343-4914			
Street Address		FAX Number (including area c	ode)		
539 Pasadena Avenue South		TAX Number (including area c	.oue)		
339 I asadena Avende South					
City		State / Province		ZIP Code	Country
St. Petersburg		FL		33707	USA
Contact Name	Contact Title			Contact E-mail A	ddress
Joe Morrison	Operations Manager				
Joe Monison	Operations Manager			joemorrison@re	eooux.net
Facility Facebilish and blackfing (F	ED November				
Original Facility Establishment Identifier (F	EI) Number	Manufacturer	Co	ntract Sterilizer	
Add Delete		Contract Manufacturer	Re	packager / Relab	eler
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Street Address		FAX Number (including area c	ode)		
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Contact Name	Contact Title			Contact E-mail A	ddress

FORM FDA 3514 (1/13) Add Continuation Page Page 4 of 6 Pages

Case 3:21-cv-034	<u> 196-AMO Documen</u>	<u>l 230-14 Filed 05/1</u>	<u>//24 Page 15 0/45                                  </u>	
<b>Note:</b> Submission of this information does not 2891a Device Establishment Registration form		or FDA Document Number (if kr	own)	
•				
SECTION H (Continued)  Facility Establishm	ent Identifier (FEI) Number			
Original		Manufacturer	Contract Sterilizer	
Add Delete		Contract Manufacturer	Repackager / Relabeler	- 4
Company / Institution Name		Establishment Registration N	umber	
Division Name (if applicable)		Phone Number (including are	a code)	
Ctrant Address		5.0VAL 1 (1 1 1 1	4.3	
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City		State / Province	ZIP Code Country	
Contact Name	Contact Title		Contact E-mail Address	
— Facility Establishm	ent Identifier (FEI) Number			
Original		Manufacturer	Contract Sterilizer	
Add Delete		Contract Manufacturer	Repackager / Relabeler	
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Street Address		FAX Number (including area	code)	
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Original Delete		Manufacturer  Contract Manufacturer	Contract Sterilizer  Repackager / Relabeler	
Company / Institution Name		Establishment Registration N	umber	
Division Name (if applicable)		Phone Number (including are	a code)	
Street Address		FAX Number (including area	rode)	
		TAX Number (moraling area	3040)	
City		State / Province	ZIP Code Country	
Contact Name	Contact Title		Contact E-mail Address	

FORM FDA 3514 (1/13) Add Continuation Page Page 5 of 6 Pages

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#### SECTION I UTILIZ

#### **UTILIZATION OF STANDARDS**

**Note:** Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

Standards No.	Standards	Standards Title	Version	Date
60601-1	Organization AAMI ANSI	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	Third Edition 2012	
Standards No. 60601-1-2	Standards Organization IEC	Standards Title  Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests	Version Third Edition 2007	Date
Standards No. 60601-2-2	Standards Organization IEC	Standards Title  Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories	Version Fifth Edition 2009	Date
Standards No. 10993-1	Standards Organization ISO	Standards Title  Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process	Version Fourth Edition 2009-10-15	Date
Standards No. 10993-5	Standards Organization AAMI ANSI ISO	Standards Title  Biological Evaluation Of Medical Devices Part 5: Tests For In  Vitro Cytotoxicity	Version 2009/(R) 2014	Date
Standards No. 10993-10	Standards Organization ISO	Standards Title  Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	Version Third Edition 2010-08-01	Date
Standards No. 10993-11	Standards Organization ISO	Standards Title  Biological Evaluation Of Medical Devices Part 11: Tests For Systemic Toxicity	Version Second Edition 2006-08-15	Date

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

#### \*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.\*

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff 1350 Piccard Drive, Room 400 Rockville, MD 20850

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FORM FDA 3514 (1/13) Page 6 of 6 Pages

Attachment A-3 Addendum to FDA Form 3514

## Addendum to Form FDA 3514

Table A-1 Model Numbers continued from Section F:

#	Trade or Proprietary or Model Name	Model Number
	for This Device	
6	Cadiere Forceps	420049
7	ProGrasp <sup>™</sup> Forceps	420093
8	PreCise™ Bipolar Forceps	420110
9	Micro Bipolar Forceps	420171
10	Maryland Bipolar Forceps	420172
11	Curved Scissors	420178
12	Hot Shears <sup>TM</sup> (Monopolar Curved	420179
	Scissors)	
13	Resano Forceps	420181
14	Permanent Cautery Hook	420183
15	Permanent Cautery Spatula	420184
16	Double Fenestrated Grasper	420189
17	Cobra Grasper	420190
18	Mega™ Needle Driver	420194
19	Fenestrated Bipolar Forceps	420205
20	Tenaculum Forceps	420207
21	PK® Dissecting Forceps	420227
22	Large SutureCut <sup>TM</sup> Needle Driver	420296
23	Mega SutureCut <sup>TM</sup> Needle Driver	420309
24	Curved Bipolar Dissector	420344

Table A-2 Standards Utilized Continued from Section I

Standards No.	Standards Organization	Standards Title	Version
10993-4	ISO	Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood	2002
F756-13	ASTM	Standard Practice For Assessment Of Hemolytic Properties Of Materials. (Biocompatibility)	2013

Attachment A-4 – Indications For Use

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

## **Indications for Use**

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

510(k) Number (if known)
Device Name Re-manufactured EndoWrists
Re-manufactured Endowrists
ndications for Use (Describe)
EndoWrist® Instruments, including scissors, scalpels, forceps, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.
The Instrument is for use only with the Intuitive da Vinci® S and da Vinci® Si Systems (Endoscopic Instrument Control System).
Time of the (Colort are suboth as emiliable)
Type of Use (Select one or both, as applicable)
Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)
We assume any factor of the fa

#### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

#### \*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Attachment A-5 – 510(k) Summary

# 510(k) SUMMARY (as required by 807.92)

#### I. SUBMITTER

Rebotix, LLC

539 Pasadena Ave. S.

Saint Petersburg, FL 33707

Phone: 727-343-4914

Contact Person: Joe Morrison Date Prepared: 12/18/2014

#### REGULATORY CORRESPONDENT

AJW Technology Consultants, Inc 445 Apollo Beach, Blvd Apollo Beach, FL 33572

Phone: 813-645-2855 Fax: 813-645-2856

Contact Person: Ryan Burke

Email: rburke@ajwtech.com

#### II. DEVICE

Name of Device: Re-manufactured EndoWrists

Common or Usual Name/

Classification Name: Endoscopic instrument control system, endoscopic

instruments and accessories

**Device Panel:** General & Plastic Surgery

**Regulatory Class:** Class II **Product Code:** NAY

#### III. PREDICATE DEVICE

The Re-manufactured EndoWrists are substantially equivalent in intended use and similar technological characteristics of the Intuitive Surgical Endoscopic Instrument Control System (Model IS2000) and EndoWrist Endoscopic Instruments as part of K063220, and the Intuitive Surgical, Inc. da Vinci Si Surgical System (Model IS3000) which was cleared under K081137.

These predicates have not been subject to a design-related recall. No reference devices were used in this submission

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#### IV. DEVICE DESCRIPTION

The Re-Manufactured EndoWrists are multiple-use endoscopic instruments to be used in conjunction with the Intuitive Surgical Endoscopic Instrument Control System. The subject device(s) consist of a family of endoscopic instruments with either grasping or cutting end effectors to be used with the Intuitive Surgical da Vinci Endoscopic Instrument Control System. These instruments attach to the instrument manipulator arms on the Intuitive Surgical Endoscopic Instrument Control System. The instruments are re-usable (for a limited number of uses), are provided non-sterile, and must be cleaned and sterilized before used (pre-vacuum autoclave). The instruments are programmed for a limited number of uses to ensure reliability and consistent performance.

The instruments attach to disposable, sterile adaptor on the manipulator arm of the Endoscopic Instrument Control System to provide a barrier between the (sterile) instrument and the (non-sterile) manipulator arm. This allows instruments to be interchangeable during a procedure, without compromising the sterile barrier. When attached to the manipulator, the instrument is inserted through a cannula mounted to the manipulator.

All instruments have articulations at the distal end that are controlled by the surgeon. The instrument is the "wrist" of the system and provides four (4) degrees of freedom (wrist pitch, wrist yaw, rotation and grip). These instruments share similar architecture, materials, and manufacturing processes. The primary difference between the instruments is the tip end effector also known as the "tool end".

#### V. INDICATIONS FOR USE

EndoWrist® Instruments, including scissors, scalpels, forceps, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

The Instrument is for use only with the Intuitive da Vinci® S and da Vinci® Si Systems (Endoscopic Instrument Control System).

# VI. <u>COMPARISON OF TECHNOLIGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE</u>

The minor modifications that are made to the EndoWrists during the remanufacturing process serve only to restore them to OEM-equivalent performance specifications, and therefore do not represent changes to the technological characteristics of the devices.

#### VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

### **Biocompatibility Testing**

The product contact materials utilized in the Re-manufactured EndoWrists have been well characterized chemically and physically and have a long history of safe use in predicate devices. In addition, all patient contact components have been FDA cleared through the 510(k) Premarket Notification process and have been tested for biocompatibility.

### **Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the Re-manufactured EndoWrists devices. The devices continue to comply with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

#### **Software Verification and Validation Testing**

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw could directly result in minor injury to the patient or operator.

#### VIII. CONCLUSIONS

The testing completed demonstrates that the Re-manufactured EndoWrists exhibits comparable technical and functional characteristics to the predicate devices. Based on those characteristics, the Re-manufactured EndoWrists are substantially equivalent to the predicate device in safety and effectiveness in addition to having the same intended use.

<u>Attachment A-6 – Truthful and Accuracy Statement</u>

# PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

(As Required By 21 CFR 807.87(k))

I certify that, in my capacity as Managing Member of *Rebotix*, *LLC*, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Demo R Mixaga

Name (Print or Type)

12/18/14 Date

Premarket Notification 510(k)

Attachment A-7 – Standards Data Report Form (3654)

	REPORT FOR 510(k)s  n by applicant)		
This report and the Summary Report Table are to be compences a national or international standard. A separate repor			
TYPE OF 510(K) SUBMISSION  Traditional Special	Abbreviated		
STANDARD TITLE <sup>1</sup> AAMI ANSI ES60601-1:2005/(R)2012 And A1:2012 Medical Ele Safety And Essential Performance	ctrical Equipment - Part 1: General Requireme	nts For I	Basic
Please answer the following questions		Yes	No
Is this standard recognized by FDA <sup>2</sup> ?		$\boxtimes$	
FDA Recognition number <sup>3</sup>		# <u>19-4</u>	
Was a third party laboratory responsible for testing conformin the 510(k)?		$\boxtimes$	
Is a summary report <sup>4</sup> describing the extent of conformance 510(k)?		$\boxtimes$	
Does the test data for this device demonstrate conformity to pertains to this device?		$\boxtimes$	
Does this standard include acceptance criteria?		$\boxtimes$	
Does this standard include more than one option or selection If yes, report options selected in the summary report table.	n of tests?		$\boxtimes$
Were there any deviations or adaptations made in the use of the light of the second se			$\boxtimes$
Were deviations or adaptations made beyond what is specifing lf yes, report these deviations or adaptations in the summar			$\boxtimes$
Were there any exclusions from the standard?  If yes, report these exclusions in the summary report table.			$\boxtimes$
Is there an FDA guidance <sup>6</sup> that is associated with this stand If yes, was the guidance document followed in preparation of Title of guidance:	of this 510k?		
The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm  The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the	address of the test laboratory or certification body invassessment to this standard. The summary report incall standards utilized during the development of the d  The supplemental information sheet (SIS) is additional is necessary before FDA recognizes the standard. For www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandard.  The online search for CDRH Guidance Documents can http://www.fda.gov/MedicalDevices/DeviceRegulation GuidanceDocuments/default.htm	cludes infor evice. al informati ound at http ards/searc an be found	mation on ion which o:// h.cfm d at

	EXTENT OF STANDARD ( SUMMARY REPOR			
STANDARD TITLE AAMI ANSI ES60601 Safety And Essential P	-1:2005/(R)2012 And A1:2012 Medical Electrical erformance	l Equipment - Part 1: General R	Requirements For B	asic
	CONFORMANCE WITH STAN	DARD SECTIONS*		
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	□ N/A
TYPE OF DEVIATION OF	OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	□ N/A
TYPE OF DEVIATION OF	OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	□ N/A
TYPE OF DEVIATION OF	OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
explanation is needed described and adequ selected when follow	all sections of the standard and indicate whether d under "justification." Some standards include opately justified as appropriate for the subject device ng a standard is required under "type of deviation e page may be necessary.	ions, so similar to deviations, the. Explanation of all deviations o	e option chosen ne or description of opti	eds to be ons
	an include an exclusion of a section in the standa S), a deviation to adapt the standard to the device			al
	This section applies only to requirements of the	Paperwork Reduction Act of 1995		
*DO	NOT SEND YOUR COMPLETED FORM TO THI	E PRA STAFF EMAIL ADDRES	SS BELOW.*	
instructions, search information. Send suggestions for redu	r this collection of information is estimated to a existing data sources, gather and maintain the comments regarding this burden estimate or articing this burden, to:	data needed and complete and	d review the collec	ction of
Food and Office of Paperwo	ent of Health and Human Services I Drug Administration Chief Information Officer rk Reduction Act (PRA) Staff Cofda.hhs.gov	"An agency may not cond a person is not require collection of information currently valid OMB o	ed to respond to, a unless it displays a	

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by the applicant when submitting a submitting a suired for each standard referenced in Abbreviated  2: General Requirements For Basic Safe rements And Tests	n the 5	10(k).
2: General Requirements For Basic Safe rements And Tests	Yes	
2: General Requirements For Basic Safe rements And Tests	Yes	
rements And Tests	Yes	
		No
	$\boxtimes$	
	<del>4</del> 19-1	
e device to this standard identified	$\boxtimes$	
standard used included in the		
	$\boxtimes$	
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sts?		$\boxtimes$
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sment to this standard. The summary report incl ndards utilized during the development of the de upplemental information sheet (SIS) is additiona essary before FDA recognizes the standard. For accessdata.fda.gov/scripts/cdrh/cfdocs/cfStanda nline search for CDRH Guidance Documents ca	udes infor evice. I informati und at http irds/searcl n be found	on which o:// h.cfm
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE				
	3: 2007-03 Medical Electrical Equipment - Par al Standard: Electromagnetic Compatibility - R		Basic Safety And	l Essential
	CONFORMANCE WITH STA	ANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE		CONFORMANCE	?
			Yes N	lo N/A
TYPE OF DEVIATION OF	OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE	
TYPE OF DEVIATION OF	OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE	_
TYPE OF DEVIATION OF	OPTION SELECTED *		,	
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JUSTIFICATION				
explanation is needed described and adequ selected when follow	all sections of the standard and indicate whether all under "justification." Some standards include cately justified as appropriate for the subject deving a standard is required under "type of deviation of the page may be necessary.	options, so similar to deviations, the ice. Explanation of all deviations of	e option chosen r description of o	needs to be ptions
	an include an exclusion of a section in the stand S), a deviation to adapt the standard to the devi			ntal
	This section applies only to requirements of t	he Paperwork Reduction Act of 1995		
	NOT SEND YOUR COMPLETED FORM TO T			
The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:				
Food and Office of Paperwo	ent of Health and Human Services I Drug Administration Chief Information Officer rk Reduction Act (PRA) Staff Cofda.hhs.gov	"An agency may not cond a person is not require collection of information currently valid OMB o	ed to respond to, a unless it displays	

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	REPORT FOR 510(k)s  n by applicant)		
This report and the Summary Report Table are to be compences a national or international standard. A separate report			
TYPE OF 510(K) SUBMISSION  Traditional Special	Abbreviated		
STANDARD TITLE <sup>1</sup> IEC 60601-2-2 Edition 5.0 2009-02 Medical Electrical Equipment Essential Performance Of High Frequency Surgical Equipment And		asic Safe	ty And
Please answer the following questions		Yes	No
Is this standard recognized by FDA <sup>2</sup> ?		$\boxtimes$	
FDA Recognition number <sup>3</sup>		#6-228	
Was a third party laboratory responsible for testing conformi in the 510(k)?	-	$\boxtimes$	
Is a summary report <sup>4</sup> describing the extent of conformance 510(k)?		$\boxtimes$	
Does the test data for this device demonstrate conformity to pertains to this device?		$\boxtimes$	
Does this standard include acceptance criteria?			
Does this standard include more than one option or selection If yes, report options selected in the summary report table.	n of tests?		$\boxtimes$
Were there any deviations or adaptations made in the use o If yes, were deviations in accordance with the FDA supplem			
Were deviations or adaptations made beyond what is specif If yes, report these deviations or adaptations in the summary			$\boxtimes$
Were there any exclusions from the standard?  If yes, report these exclusions in the summary report table.			$\boxtimes$
Is there an FDA guidance <sup>6</sup> that is associated with this stand If yes, was the guidance document followed in preparation of Title of guidance:	of this 510k?		
The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm  The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the	address of the test laboratory or certification body invassessment to this standard. The summary report incall standards utilized during the development of the d  The supplemental information sheet (SIS) is additionally is necessary before FDA recognizes the standard. For www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStand  The online search for CDRH Guidance Documents on http://www.fda.gov/MedicalDevices/DeviceRegulation GuidanceDocuments/default.htm	cludes infor evice. al informati bund at http ards/searci an be found	mation on on which o:// h.cfm d at

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE				
	5.0 2009-02 Medical Electrical Equipment - Of High Frequency Surgical Equipment And			
	CONFORMANCE WITH ST	ANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
			Yes No N/A	
TYPE OF DEVIATION OF	OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
TYPE OF DEVIATION OF	OPTION SELECTED *			
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TYPE OF DEVIATION OF	OPTION SELECTED *			
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explanation is needed described and adequ selected when follow	all sections of the standard and indicate whet d under "justification." Some standards include ately justified as appropriate for the subject de ng a standard is required under "type of deviate e page may be necessary.	options, so similar to deviations, th vice. Explanation of all deviations o	e option chosen needs to be r description of options	
	an include an exclusion of a section in the star S), a deviation to adapt the standard to the de			
	This section applies only to requirements of	the Paperwork Reduction Act of 1995		
*DO	NOT SEND YOUR COMPLETED FORM TO	THE PRA STAFF EMAIL ADDRES	S BELOW.*	
The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:				
Food and Office of Paperwo	ent of Health and Human Services I Drug Administration Chief Information Officer rk Reduction Act (PRA) Staff Cofda.hhs.gov	"An agency may not cond a person is not require collection of information currently valid OMB o	ed to respond to, a unless it displays a	

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	REPORT FOR 510(k)s n by applicant)		
This report and the Summary Report Table are to be compences a national or international standard. A separate repor			
TYPE OF 510(K) SUBMISSION  Traditional  Special	Abbreviated		
STANDARD TITLE <sup>1</sup> ISO 10993-1 Fourth Edition 2009-10-15 Biological Evaluation Of Management Process	Medical Devices - Part 1: Evaluation And Tes	ting With	nin A Risk
Please answer the following questions		Yes	No
Is this standard recognized by FDA <sup>2</sup> ?		$\boxtimes$	
FDA Recognition number <sup>3</sup>		#2-179	
Was a third party laboratory responsible for testing conform in the 510(k)?		$\boxtimes$	
Is a summary report <sup>4</sup> describing the extent of conformance 510(k)?		$\boxtimes$	
Does the test data for this device demonstrate conformity to pertains to this device?		$\boxtimes$	
Does this standard include acceptance criteria?			
Does this standard include more than one option or selection If yes, report options selected in the summary report table.	on of tests?		$\boxtimes$
Were there any deviations or adaptations made in the use of the second o			
Were deviations or adaptations made beyond what is specifing or specifications or adaptations in the summar			$\boxtimes$
Were there any exclusions from the standard?  If yes, report these exclusions in the summary report table.			$\boxtimes$
Is there an FDA guidance <sup>6</sup> that is associated with this stand If yes, was the guidance document followed in preparation of Title of guidance: ODE General Program Memorandum #G95-1	of this 510k?		
The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm  The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and	address of the test laboratory or certification body invassessment to this standard. The summary report in all standards utilized during the development of the companies of the supplemental information sheet (SIS) is addition is necessary before FDA recognizes the standard. For www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStand The online search for CDRH Guidance Documents of http://www.fda.gov/MedicalDevices/DeviceRegulation GuidanceDocuments/default.htm	cludes infor levice. al informati ound at http ards/searci an be found	mation on on which o:// h.cfm d at

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE				
STANDARD TITLE ISO 10993-1 Fourth Ed Management Process	dition 2009-10-15 Biological Evaluation Of Medical Devices - Part 1: Ex	valuation And Testing Within A Risk		
	CONFORMANCE WITH STANDARD SECTIONS*			
SECTION NUMBER	SECTION TITLE	CONFORMANCE?		
		Yes No N/A		
TYPE OF DEVIATION OF	R OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE	CONFORMANCE?		
TYPE OF DEVIATION OF	R OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE	CONFORMANCE?		
TYPE OF DEVIATION OF	ROPTION SELECTED *	,		
DESCRIPTION				
JUSTIFICATION				
explanation is needed described and adequ selected when follow	t all sections of the standard and indicate whether conformance is met. If a dunder "justification." Some standards include options, so similar to devia ately justified as appropriate for the subject device. Explanation of all deving a standard is required under "type of deviation or option selected," "defenge may be necessary.	ations, the option chosen needs to be iations or description of options		
	can include an exclusion of a section in the standard, a deviation brought S), a deviation to adapt the standard to the device, or any adaptation of a			
	This section applies only to requirements of the Paperwork Reduction Ac	t of 1995.		
*DO	NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL A	ADDRESS BELOW.*		
instructions, search information. Send suggestions for redu	or this collection of information is estimated to average 1 hour per responsive existing data sources, gather and maintain the data needed and complete comments regarding this burden estimate or any other aspect of this burden, to:	plete and review the collection of		
Food and Office of Paperwo	d Drug Administration  f Chief Information Officer  a person is no collection of in,	y not conduct or sponsor, and ot required to respond to, a formation unless it displays a lid OMB control number."		

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	REPORT FOR 510(k)s n by applicant)		
This report and the Summary Report Table are to be compences a national or international standard. A separate repor			
TYPE OF 510(K) SUBMISSION  Traditional  Special	Abbreviated		
STANDARD TITLE <sup>1</sup> AAMI ANSI ISO 10993-5:2009/(R) 2014 Biological Evaluation C	Of Medical Devices Part 5: Tests For In Vitro	Cytotox	icity
Please answer the following questions		Yes	No
Is this standard recognized by FDA <sup>2</sup> ?		$\boxtimes$	
FDA Recognition number <sup>3</sup>		#2-153	
Was a third party laboratory responsible for testing conform in the 510(k)?	-	$\boxtimes$	
Is a summary report <sup>4</sup> describing the extent of conformance 510(k)?		$\boxtimes$	
Does the test data for this device demonstrate conformity to pertains to this device?		$\boxtimes$	
Does this standard include acceptance criteria?		$\boxtimes$	
Does this standard include more than one option or selection.  If yes, report options selected in the summary report table.	on of tests?		$\boxtimes$
Were there any deviations or adaptations made in the use of the last of the secondarian with the FDA supplemental suppleme			$\boxtimes$
Were deviations or adaptations made beyond what is specified or specified in the summar of the summa			$\boxtimes$
Were there any exclusions from the standard?  If yes, report these exclusions in the summary report table.			$\boxtimes$
Is there an FDA guidance <sup>6</sup> that is associated with this stand If yes, was the guidance document followed in preparation of Title of guidance:	of this 510k?		
The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm  The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the	address of the test laboratory or certification body invassessment to this standard. The summary report incall standards utilized during the development of the d  The supplemental information sheet (SIS) is additionally is necessary before FDA recognizes the standard. For www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandard.  The online search for CDRH Guidance Documents on http://www.fda.gov/MedicalDevices/DeviceRegulation	cludes infor evice. al informati ound at http ards/searcl an be found	mation on on which o:// h.cfm d at

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE						
STANDARD TITLE AAMI ANSI ISO 1099	STANDARD TITLE  AAMI ANSI ISO 10993-5:2009/(R) 2014 Biological Evaluation Of Medical Devices Part 5: Tests For In Vitro Cytotoxicity					
	CONFORMANCE WITH	STANDARD SECTIONS*				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION OF	OPTION SELECTED *		Yes No N/A			
THE OF BEVIATION OF	(O) HONOLLEGIED					
DESCRIPTION						
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION OF	OPTION SELECTED *					
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JUSTIFICATION						
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION OF	OPTION SELECTED *					
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	can include an exclusion of a section in the S), a deviation to adapt the standard to the		e FDA supplemental			
		ts of the Paperwork Reduction Act of 1995.				
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instructions, search information. Send suggestions for red	or this collection of information is estimated existing data sources, gather and maintacomments regarding this burden estimated this burden, to:	ain the data needed and complete and	review the collection of			
Food an Office o Paperwo	nent of Health and Human Services  d Drug Administration  f Chief Information Officer  ork Reduction Act (PRA) Staff  ##################################	"An agency may not cond a person is not require collection of information currently valid OMB o	d to respond to, a unless it displays a			

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STANDARDS DATA (To be filled in	REPORT FOR 510(k)s n by applicant)		
This report and the Summary Report Table are to be compences a national or international standard. A separate repor			
TYPE OF 510(K) SUBMISSION  ☑ Traditional ☐ Special	Abbreviated		
STANDARD TITLE <sup>1</sup> ISO 10993-10 Third Edition 2010-08-01 Biological Evaluation Of Sensitization	Medical Devices - Part 10: Tests For Irritation	And Ski	n
Please answer the following questions		Yes	No
Is this standard recognized by FDA <sup>2</sup> ?		$\boxtimes$	
FDA Recognition number <sup>3</sup>		#2-174	
Was a third party laboratory responsible for testing conform in the 510(k)?		$\boxtimes$	
Is a summary report <sup>4</sup> describing the extent of conformance 510(k)?		$\boxtimes$	
Does the test data for this device demonstrate conformity to pertains to this device?		$\boxtimes$	
Does this standard include acceptance criteria?			
Does this standard include more than one option or selection of the summary report table.	on of tests?		$\boxtimes$
Were there any deviations or adaptations made in the use of the secondarial of the second			
Were deviations or adaptations made beyond what is specified of the specified of the summar of the s			$\boxtimes$
Were there any exclusions from the standard?  If yes, report these exclusions in the summary report table.			$\boxtimes$
Is there an FDA guidance <sup>6</sup> that is associated with this stand If yes, was the guidance document followed in preparation of Title of guidance:	of this 510k?		
The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm  The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the	address of the test laboratory or certification body invassessment to this standard. The summary report incall standards utilized during the development of the difference of the supplemental information sheet (SIS) is addition is necessary before FDA recognizes the standard. For www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStand  The online search for CDRH Guidance Documents of http://www.fda.gov/MedicalDevices/DeviceRegulation GuidanceDocuments/default.htm	cludes infor levice. al informati bund at http ards/searcl an be found	on which o:// h.cfm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE				
STANDARD TITLE ISO 10993-10 Third E Sensitization	dition 2010-08-01 Biological Evaluation Of	Medical Devices - Part 10: Tests For	Irritation And Skin	
	CONFORMANCE WITH	STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
TYPE OF DEVIATION OF	OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
TYPE OF DEVIATION OF	OPTION SELECTED *			
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SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
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	This section applies only to requirements	of the Paperwork Reduction Act of 1995.		
	NOT SEND YOUR COMPLETED FORM TO			
instructions, search information. Send suggestions for red	r this collection of information is estimated existing data sources, gather and maintain comments regarding this burden estimated using this burden, to: ent of Health and Human Services	n the data needed and complete and	l review the collection of	
Food and Office of Paperwo	and Human Services  I Drug Administration Chief Information Officer Reduction Act (PRA) Staff Cafda.hhs.gov	"An agency may not cond a person is not require collection of information currently valid OMB o	d to respond to, a unless it displays a	

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	REPORT FOR 510(k)s n by applicant)		
This report and the Summary Report Table are to be compences a national or international standard. A separate repor			
TYPE OF 510(K) SUBMISSION			
⊠ Traditional ☐ Special	Abbreviated		
STANDARD TITLE <sup>1</sup> ISO 10993-11 Second Edition 2006-08-15 Biological Evaluation C	Of Medical Devices Part 11: Tests For Systemi	c Toxicit	у
Please answer the following questions		Yes	No
Is this standard recognized by FDA <sup>2</sup> ?		$\boxtimes$	
FDA Recognition number <sup>3</sup>		#2-176	_
Was a third party laboratory responsible for testing conform in the 510(k)?		$\boxtimes$	
Is a summary report <sup>4</sup> describing the extent of conformance 510(k)?		$\boxtimes$	
Does the test data for this device demonstrate conformity to pertains to this device?		$\boxtimes$	
Does this standard include acceptance criteria?			
Does this standard include more than one option or selection of the summary report table.	on of tests?		$\boxtimes$
Were there any deviations or adaptations made in the use of lifyes, were deviations in accordance with the FDA supplemental supplementa			
Were deviations or adaptations made beyond what is specified lf yes, report these deviations or adaptations in the summar			$\boxtimes$
Were there any exclusions from the standard?  If yes, report these exclusions in the summary report table.			
Is there an FDA guidance <sup>6</sup> that is associated with this stand If yes, was the guidance document followed in preparation of Title of guidance:			
The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm	address of the test laboratory or certification body invassessment to this standard. The summary report in all standards utilized during the development of the of The supplemental information sheet (SIS) is addition is necessary before FDA recognizes the standard. For	cludes infor levice. al informati ound at http	rmation on ion which o://
<sup>3</sup> http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm <sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStand <sup>6</sup> The online search for CDRH Guidance Documents c http://www.fda.gov/MedicalDevices/DeviceRegulation GuidanceDocuments/default.htm	an be foun	d at

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE						
STANDARD TITLE ISO 10993-11 Second	STANDARD TITLE ISO 10993-11 Second Edition 2006-08-15 Biological Evaluation Of Medical Devices Part 11: Tests For Systemic Toxicity					
	CONFORMANCE WITH	STANDARD SECTIONS*				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION OF	OPTION SELECTED *		Secretary Secretary Manual			
DESCRIPTION						
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION OF	OPTION SELECTED *					
DESCRIPTION						
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		ts of the Paperwork Reduction Act of 1995.				
	NOT SEND YOUR COMPLETED FORM T					
instructions, search information. Send suggestions for red	or this collection of information is estimated existing data sources, gather and maintage comments regarding this burden estimated using this burden, to:	ain the data needed and complete and	review the collection of			
Food and Office o Paperwo	nent of Health and Human Services  d Drug Administration  f Chief Information Officer  ork Reduction Act (PRA) Staff  ##################################	"An agency may not cond a person is not require collection of information currently valid OMB o	d to respond to, a unless it displays a			

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	REPORT FOR 510(k)s in by applicant)		
This report and the Summary Report Table are to be compenses a national or international standard. A separate repo			
TYPE OF 510(K) SUBMISSION			
∑ Traditional	Abbreviated		
STANDARD TITLE <sup>1</sup> ISO 10993-4:2002 Biological evaluation of medical devices Par	t 4: Selection of tests for interactions with bloo	d	
Please answer the following questions		Yes	No
Is this standard recognized by FDA <sup>2</sup> ?			$\boxtimes$
FDA Recognition number <sup>3</sup>		#	
Was a third party laboratory responsible for testing conform in the 510(k)?		$\boxtimes$	
Is a summary report <sup>4</sup> describing the extent of conformance 510(k)?		$\boxtimes$	
Does the test data for this device demonstrate conformity to pertains to this device?		$\boxtimes$	
Does this standard include acceptance criteria?		$\boxtimes$	
Does this standard include more than one option or selection of the summary report table.	on of tests?		$\boxtimes$
Were there any deviations or adaptations made in the use of the liftyes, were deviations in accordance with the FDA supplements.			
Were deviations or adaptations made beyond what is speci If yes, report these deviations or adaptations in the summar			$\boxtimes$
Were there any exclusions from the standard?  If yes, report these exclusions in the summary report table.			$\boxtimes$
Is there an FDA guidance <sup>6</sup> that is associated with this stand of the standard of the standar			
The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm  The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and	address of the test laboratory or certification body inv assessment to this standard. The summary report inc all standards utilized during the development of the d   The supplemental information sheet (SIS) is additional is necessary before FDA recognizes the standard. For www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandard.  The online search for CDRH Guidance Documents can http://www.fda.gov/MedicalDevices/DeviceRegulation GuidanceDocuments/default.htm	cludes infor evice. al informati ound at http ards/searci an be found	mation on on which o:// h.cfm d at

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE						
STANDARD TITLE ISO 10993-4:2002 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood						
CONFORMANCE WITH STANDARD SECTIONS*						
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION OF	OPTION SELECTED *					
DESCRIPTION						
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION OF	OPTION SELECTED *					
DESCRIPTION						
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION OF	OPTION SELECTED *					
DESCRIPTION						
JUSTIFICATION						
explanation is neede described and adequ selected when follow	all sections of the standard and indicate we under "justification." Some standards incleately justified as appropriate for the subjecting a standard is required under "type of deepage may be necessary.	ude options, so similar to deviations, the t device. Explanation of all deviations of	e option chosen needs to be r description of options			
* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.						
		ts of the Paperwork Reduction Act of 1995.				
*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*						
The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:						
Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov  "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."						

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STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)					
This report and the Summary Report Table are to be compences a national or international standard. A separate repor					
TYPE OF 510(K) SUBMISSION					
⊠ Traditional ☐ Special	Abbreviated				
STANDARD TITLE <sup>1</sup> ASTM F756-13, Standard Practice For Assessment Of Hemolytic 2	Properties Of Materials. (Biocompatibility)				
Please answer the following questions		Yes	No		
Is this standard recognized by FDA <sup>2</sup> ?		$\boxtimes$			
FDA Recognition number <sup>3</sup>		#2-207			
Was a third party laboratory responsible for testing conform in the 510(k)?		$\boxtimes$			
Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)?					
Does the test data for this device demonstrate conformity to pertains to this device?	$\boxtimes$				
Does this standard include acceptance criteria?					
Does this standard include more than one option or selection of the summary report table.	on of tests?				
Were there any deviations or adaptations made in the use of the standard?					
Were deviations or adaptations made beyond what is specified lf yes, report these deviations or adaptations in the summar			$\boxtimes$		
Were there any exclusions from the standard?  If yes, report these exclusions in the summary report table.					
Is there an FDA guidance <sup>6</sup> that is associated with this stand If yes, was the guidance document followed in preparation of Title of guidance:					
The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm  The formatting convention for the title is: [SDO] [numeric identifier] [title of standards] [tit	address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.  The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://				
<ul> <li>http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</li> <li>The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and</li> <li>The online search for CDRH Guidance Documents can http://www.fda.gov/MedicalDevices/DeviceRegulationan GuidanceDocuments/default.htm</li> </ul>			d at		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE						
STANDARD TITLE ASTM F756-13, Standard Practice For Assessment Of Hemolytic Properties Of Materials. (Biocompatibility)						
CONFORMANCE WITH STANDARD SECTIONS*						
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION OF	OPTION SELECTED *					
DESCRIPTION						
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION OF	OPTION SELECTED *					
DESCRIPTION						
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION OF	OPTION SELECTED *					
DESCRIPTION						
JUSTIFICATION						
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.						
* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.						
		s of the Paperwork Reduction Act of 1995.				
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